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(54) **Arrhythmia recorder**

(57) A device for recording and subsequently reproducing information, such as desired portions of an ECG signal, produced by a heart prior to and during the operation of an automatic implantable defibrillator takes the form of external electrodes 164 and a defibrillation pulse detector 172 from which ECG and defibrillation information is transmitted to a delay-type continually updated memory 194 or shift register (not shown). When any one of several types of arrhythmias is sensed in the ECG information by detector 192, or when a defibrillating pulse is recognised by decoder 161, the data in the memory is "permantly" recorded on magnetic tape at 184. If the received signal level is too low for a predetermined period an alarm 186 warns the patient that detection is unreliable.

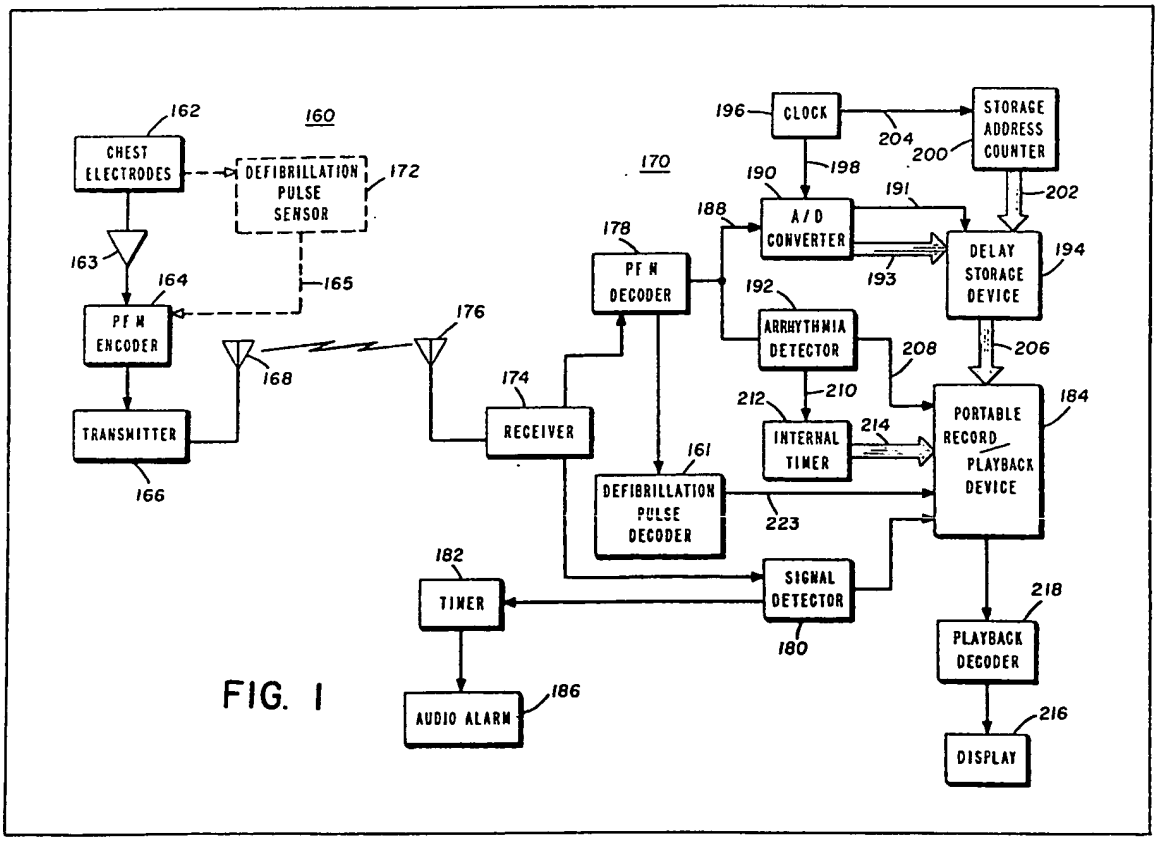

FIG. 1

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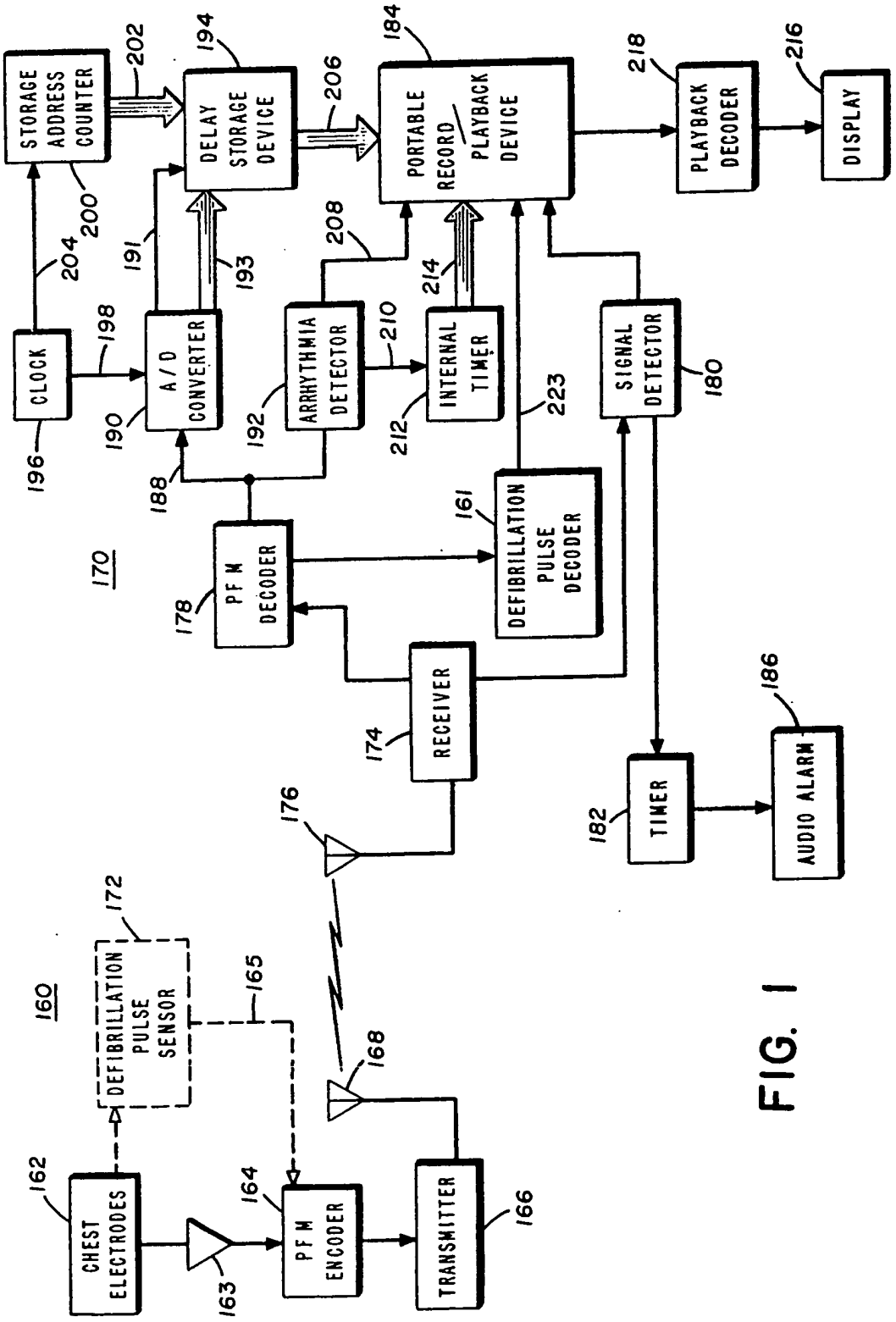
STORAGE ADDRESS COUNTER
202
DELAY STORAGE DEVICE
194
206
PORTABLE RECORD / PLAYBACK DEVICE
184
218
PLAYBACK DECODER
216
DISPLAY
200
204
191
193
208
214
CLOCK
198
A / D CONVERTER
ARRHYTHMIA DETECTOR
210
INTERNAL TIMER
SIGNAL DETECTOR
180
196
190
192
212
223
188
170
PF M DECODER
178
161
DEFIBRILLATION PULSE DECODER
RECEIVER
174
176
TIMER
182
AUDIO ALARM
186
160
DEFIBRILLATION PULSE SENSOR
172
165
168
CHEST ELECTRODES
162
163
164
PF M ENCODER
TRANSMITTER
166

FIG. 1

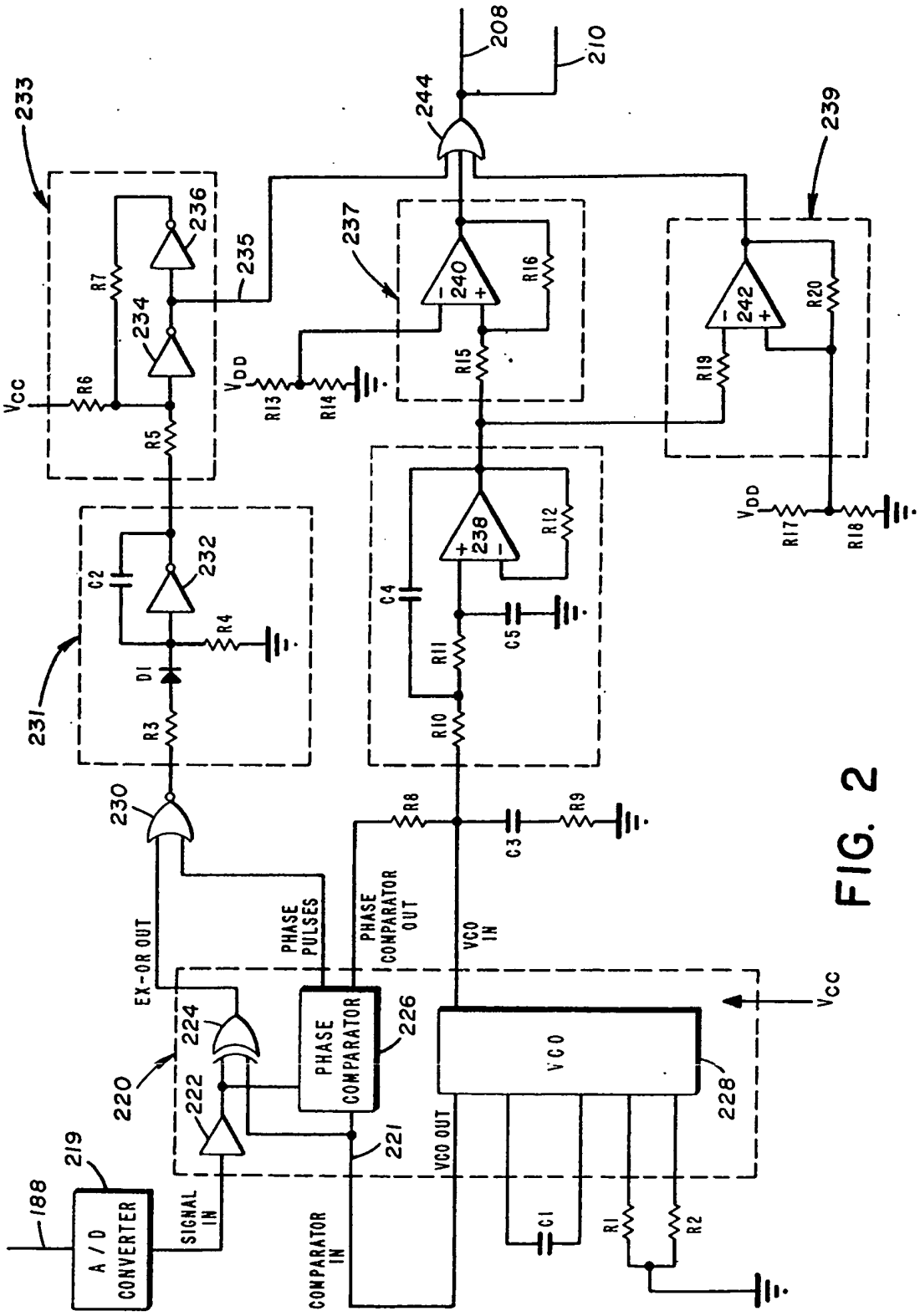
188
219
A/D CONVERTER
SIGNAL IN
COMPARATOR IN
220
222
224
221
PHASE COMPARATOR
226
VCO OUT
VCO
228
EX-OR OUT
PHASE PULSES
PHASE COMPARATOR OUT
VCO IN
230
231
232
233
234
235
236
237
239
240
242
244
208
210
R1
R2
C1
R3
D1
R4
C2
R5
R6
R7
R8
C3
R9
R10
R11
C4
C5
R12
R13
R14
R15
R16
R17
R18
R19
R20
238
V_{CC}
V_{DD}

FIG. 2

SPECIFICATION
Arrhythmia recorder

The present invention relates to an external device for recording and subsequently reproducing information relating to a disturbance in cardiac electrical activity. It is contemplated to use the device to monitor an implantable defibrillator. The device takes the form of an external recorder that has external electrodes for associating with the patient; information, such as ECG, is transmitted to the recorder unit by telemetry. A delay-type continually updated memory is continuously operative. When any one of several types of arrhythmias is sensed, or when a defibrillating pulse is delivered, the data in the memory is "permanently" recorded on magnetic tape.

During the past several decades, coronary heart disease has come to occupy the first position among the causes of death in the developed areas of the world. Although the precise cause of sudden death in coronary heart disease has not yet been entirely clarified, the available evidence permits the medical field to ascribe death in the majority of these cases to a grave disturbance in cardiac electrical activity resulting in ventricular fibrillation.

While it is not possible to predict with unerring exactness which patient suffering from coronary heart disease will be the victim of sudden death, several high risk groups of patients can be recognized. For example, patients who have experienced myocardial infarction, even though they may be surviving in good health, run a substantial risk of dying suddenly, a risk several times greater than that associated with the general population. Further, if patients with myocardial infarction have a history of serious ventricular arrhythmias and/or of cardiac arrest, or if evidence of persistent myocardial irritability is present, it may be logically assumed that the risk of sudden death is increased substantially. Patients like those described above would greatly benefit from an automatic, standby or demand defibrillator.

Another recognizable class of patients particularly in need of an automatic defibrillator is the class composed of those who have not shown prior histories of myocardial infarction but who show severe symptoms of coronary heart disease, such as ventricular arrhythmias resistant to medical treatment or angina pectoris.

Finally, there are scores of individuals walking the streets today who experience recurring episodes of atrial fibrillation, atrial flutter, or tachycardia. While not life-threatening, these supra-ventricular arrhythmias can become debiliting and lead to complications, and hence require treatment when present. Such individuals require frequent electrical or pharmacological conversion under the care of their physicians to return their hearts to normal sinus rhythm.

Great strides are presently being made to develop an automatic, fully implantable ventricular defibrillator. See, for example, U.K. Patent No. 1,298,189, where the first concept of the automatic implantable ventricular defibrillator is described. Recent advances have also been made in enhancing the reliability of fibrillation detectors. In this latter regard, see U.S. Patent No. 4,202,340. Furthermore, as outlined in U.K. patent application No. 22,917/78, filed May 26, 1978, steps have been taken to improve the reliability of the implanted defibrillator by the provision of circuitry which interrogates the implanted electronics to verify proper operation before a defibrillating shock is delivered.

Notwithstanding the substantial steps which have been taken to develop the automatic, fully implantable defibrillator and to ensure the operation of the sensing and defibrillating circuitry, it must not be forgotten that the implantable defibrillator is in its infancy. Accordingly, there is a current need for data which either verifies the accuracy or which uncovers the failings of the sensing and defibrillating circuits. Specifically, there is a need for a practical device capable of providing data by recording and subsequently reproducing desired portions of an electrocardiogram (ECG) signal produced by a heart prior to and during the occurrence of various disturbances in cardiac electrical activity. With such a device, not only could the operation of the implanted defibrillator be verified, but valuable information about the patient's heart activity prior to and during cardiac arrhythmias could be obtained. Furthermore, there is a need for a practical device which could be worn by a patient to monitor heart activity even in the absence of an implanted defibrillator.

It is toward the object of meeting the foregoing needs that the present invention is directed.

The subject invention relates in general to a device for recording and subsequently reproducing desired portions of an ECG signal produced by a heart prior to and during the occurrence of various disturbances in cardiac electrical activity. Through the use of an appropriate transducer, the electrical activity of a patient's heart is detected and converted into a typical ECG signal.

More specifically, in a preferred embodiment of the present invention, the means used to sense the heart's cardiac electrical activity as an ECG signal takes the form of chest electrodes placed on the anterior chest wall of the patient. Conventional telemetry techniques are used to broadcast the ECG signal from the patient. This signal is received for recording and subsequent playback by the circuitry of the subject invention, which is housed in a convenient container such as a briefcase. In this embodiment, the received ECG signal is converted to a convenient digital form. The digital signal representing the ECG signal is stored on a FIFO (First In, First Out) basis in a storage device having a predetermined capacity. A conventional arrhythmia detector which continuously monitors the received ECG signals produces an arrhythmia detected logic signal at the occurrence of a disturbance in cardiac electrical activity. By way of example, such a disturbance may be produced by

ventricular tachycardia, bradycardia, asystole, ventricular flutter, ventricular fibrillation, and ectopic beats. The arrhythmia detected logic signals turns on a tape recorder which records the output of the storage device. After the disturbance has ceased and the heart has returned to normal cardiac electrical activity the arrhythmia detected logic signal ceases. The recorder continues to record the output of the storage device for a predetermined time period equal, for example, to the time interval necessary for the storage device to once read out its entire contents. After this has taken place the recorder shuts down. Thus the recorder now possesses, on a magnetic tape in digital form, the desired portion of the received ECG signal produced by the heart prior to and during the occurrence of the disturbance in cardiac electrical activity.

The tape is played back by a physician or trained assistant at the physician's office or at a hospital in conjunction with a display device for subsequent interpretation.

Customarily, the term electrocardiogram (ECG) implies the use of electrodes on the body surface to obtain electrical signals indicative of heart activity. The term electrogram, on the other hand, generally refers to measurements made at the surface of the heart. As used herein, "ECG" is defined broadly, and refers to any measurement of the electrical activity of the heart, notwithstanding the source or technique of the measurement.

It is accordingly an object of the present invention to provide a device for recording and subsequently reproducing desired portions of an ECG produced by a heart prior to and during the occurrence of a disturbance in cardiac electrical activity.

It is another object of the present invention to provide a device for preserving valuable information about the patient's heart activity as represented by an ECG signal occurring prior to and during a fibrillation episode.

It is still another object of the present invention to provide a lightweight, external device employing radio telemetry techniques for recording and subsequently reproducing a desired portion of an ECG signal produced by a heart prior to and during the occurrence of a disturbance in cardiac electrical activity.

It is a further object of the present invention to provide a lightweight external device for recording and subsequently reproducing portions of ECG signals relating to multiple disturbances in cardiac electrical activity as experienced by a patient.

It is yet a further object of the present invention to provide a device for recording and subsequently reproducing information pertinent to a defibrillation attempt by an implantable defibrillator.

It is still another object of the present invention to provide a device which will aid in recognizing the need for a fully implantable ventricular defibrillator in a patient suffering from coronary heart disease, and which will aid in treatment of patients suffering from cardiac arrhythmias.

It is still a further object of the present invention to provide a device for verifying the operation of an implanted defibrillator.

Other objects and advantages of this invention will further become apparent hereinafter and in the drawings.

Figure 1 is a detailed block diagram of a preferred embodiment of the subject invention.

Figure 2 is a schematic diagram of an embodiment of the arrhythmia detector associated with the Figure 1 embodiment.

In describing the preferred embodiments of the invention illustrated in the drawings, specific terminology will be resorted to for the sake of clarity. However, it is not intended to be limited to the specific terms so selected, and it is to be understood that each specific term includes all technical equivalents which operate in a similar manner to accomplish a similar purpose.

An embodiment of the subject invention will now be described with reference to Figure 1. The device comprises two units generally designated as 160 and 170. The first unit 160 is an ECG signal transmission unit which is worn by a patient. The second unit 170 is an ECG signal receiving and processing unit, is designed to be located at some defined distance from the patient, and is housed in a convenient container such as a briefcase.

Chest electrodes 162 placed on the anterior chest wall of the patient sense the heart's cardiac electrical activity as an ECG signal, which is fed into an amplifier 163. A pulse frequency modulation (PFM) encoder 164 converts the amplified ECG signal into a PFM waveform. In this regard, the PFM waveform includes a plurality of uniform width pulses, the spacing (or frequency) of which represents the data being transmitted. The PFM waveform is fed to a transmitter 166, the output of which is fed to an antenna 168. If the patient has an implanted defibrillator, a defibrillation pulse sensor 172, shown in phantom, is included in the unit 160. The defibrillation pulse sensor receives the ECG signal from the chest electrodes. A normal ECG signal has a magnitude of approximately 1 millivolt while a cardioverting or defibrillating shock has a magnitude of approximately 10 volts measured at the skin. Thus, when the implanted defibrillator issues a cardioverting shock, the sensor 172 detects the cardioverting shock and issues a signal which is fed into the PFM encoder for PFM encoding and subsequent transmission by the transmitter 166 and antenna 168. At the same time, the signal from the sensor 172, via line 165, causes the PFM encoder 164 to provide a special signal to the transmitter indicative of the delivery of a defibrillating pulse.

A receiver 174 receives the transmitted PFM waveform via an antenna 176. The output of the receiver is fed to a pulse frequency modulation (PFM) decoder 178 and also to a signal detector 180. When the output of the receiver 174 drops below a certain level, or the demodulated pulses are not of the correct (transmitted) width, the

signal detector produces an enabling signal which is fed to a timer 182 and a disabling signal which is fed to a portable record/playback (R/P) device 184 such as a cassette recorder or the like. The timer 182 produces a signal of desired duration to activate an audio alarm 186. In this way the patient is made aware of any interruption in the transmission of ECG signals by the unit 160, or in the reception of ECG signals by the unit 170, or that he/she has entered an area of electromagnetic interference (pulse width not as transmitted). The patient is also alerted to the fact that he/she has placed the unit 160 out of the reception range of the unit 170.

The PFM decoder 178 decodes the PFM waveform received from the receiver 174 to reconstruct the ECG signal. The reconstructed ECG signal, appearing on lines 188, is fed to an analog-to-digital (A/D) converter 190, wherein the ECG signal is converted into a digital representation. The digital representation is made up of a series of words wherein each word contains eight bits. The reconstructed ECG signal, appearing on lines 188, is also fed to an arrhythmia detector 192 of known design. The particular type of arrhythmia detector chosen depends on the type or types of cardiac abnormalities to be detected. One such arrhythmia detector is discussed in detail hereinafter. The output of the A/D converter 190 is received and stored on a FIFO (First In, First Out) basis in a delay storage device 194 having a predetermined capacity. The storage device 194 may contain either a random access memory (RAM), or shift registers.

In one embodiment, the storage device 194 contains an 8K random access memory, which is capable of storing 1,024 words of digital data. These 1,024 words represent the most recent ten seconds of cardiac electrical activity as sensed by the chest electrodes 162. Thus at any time, ten seconds of the most recent ECG signal may be stored in digital form within the storage device 194. It should be pointed out that the storage capacity may be increased or decreased in order to store data produced during a greater or lesser time period.

A clock 196 provides an initiate conversion signal as well as gating pulses to the A/D converter via lines 198. A storage address (SA) counter 200 provides address codes to the storage device 194 via lines 202. The clock 196 supplies clock pulses on lines 204 to increment the SA counter. The SA counter provides address codes to sequentially address all of the storage locations in the storage device. As long as clock pulses are received on lines 204, the SA counter will continuously repeat the address sequence.

In operation, the output of the A/D converter 190 is stored in the storage device at locations determined by the address codes from the SA counter 200. Conversion is initiated and carried out in the A/D converter in response to pulses from the clock 196. When conversion is complete, the A/D converter produces a WRITE strobe on lines 191. Thus, data from the A/D converter is written into the storage device via data bus 193. After the entire RAM has been addressed, the SA counter starts the address sequence over again and new digital data from the A/D converter is written into the storage locations of the storage device 194, on a first in, first out (FIFO) basis. The storage device 194 contains read circuitry for continuously reading out the replaced digital data onto lines 206.

In a modification of the embodiment of the system of Figure 1, the storage device 194 is implemented through the use of eight 1,024-bit shift registers. In this embodiment, the storage address counter 200 is not needed. As stated before, the digital representation from the A/D converter 190 is made up of a series of words wherein each contains eight bits. The eight bits of each word are written into the first stages of the shift registers, one bit into each register, by the WRITE strobe on lines 191. The data within each shift register is sequentially shifted under the control of the clock 196. Eventually, the data is shifted to the last stage of each shift register. The data in the last stage of each shift register is shifted out onto lines 206 as a series of eight bit words. In this way new digital data replaces previously stored digital data on a first in, first out (FIFO) basis.

When the arrhythmia detector 192 detects a disturbance in cardiac electrical activity, it issues two signals, one on lines 208 and one on lines 210. The signal on lines 208 enables the record/playback device 184. The signal on lines 210 is fed to an internal timer 212, which, as an example, may be a digital watch chip. The internal timer continuously keeps track of desired information such as time and date in the form of a digital signal referred to as a time tag. The signal on lines 210 causes the internal timer 212 to issue a time tag on lines 214.

The record/playback device 184, in response to the enabling signal, records on a magnetic tape the time tag and the digital data appearing on lines 206. After the disturbance has ceased and the heart has returned to normal cardiac electrical activity, the enabling signal on lines 208 ceases. The record/playback device continues to record the output of the storage device 194 for a predetermined time period equal, for example, to the time interval necessary for the storage device to once read out its entire contents. After this has taken place, the recorder shuts down. Thus, the recorder now possesses on the magnetic tape in digital form the desired portion of the ECG signal produced by the heart prior to and during the occurrence of the disturbance in cardiac electrical activity.

Any subsequent disturbances in cardiac electrical activity are recorded in the same manner as previously described. In each case, the record/playback device 184 in response to the enabling signal, records on the magnetic tape the time tag and the digital data appearing on lines 206. The capacity of the record/playback device is

determined by the length of the magnetic tape and the speed at which a recording is made.

The defibrillation pulse sensor 172 is used in the embodiment of the invention when a patient has an implanted defibrillator. As stated previously, a normal ECG signal has a magnitude of approximately 1 millivolt while a defibrillating shock has a magnitude of approximately ten volts. The defibrillation pulse sensor 172 receives the ECG signal from the chest electrodes 162 and senses the dramatic shift in pulse magnitude caused by the deliverance of a defibrillating shock. When this shift takes place, the defibrillation pulse sensor issues a defibrillation sensed (DS) signal on lines 165. The DS signal causes the pulse frequency modulation to transmit a code not normally seen during the transmission of ECG data, such as a high pulse repetition frequency. In addition, the DS signal is received by the defibrillation pulse decoder 161 after being encoded, transmitted, received, and decoded in the manner previously described with regard to ECG signals from the chest electrodes 162. The defibrillation pulse decoder 161 interprets the DS signal as an event to be recorded, and in response thereto issues the signal on lines 223 to enable the record/playback device 184 and the signal on line 210 to cause the internal timer 212 to issue a time tag.

At some point in time, the tape in the record/playback device 184 is rewound and then played back by a physician or trained assistant at the doctor's office or at a hospital. It is contemplated that the physician and the hospital will have playback equipment so that the patient is able to mail his/her cassette for interpretation. For convenience, however, the playback function is integrated with the receiving and recording functions. The information on the tape is fed to a display 216 via a playback decoder 218 to display the information in an eye-readable format for subsequent interpretation. The playback decoder 218 contains circuitry for converting the digital data on the tape into a series of driving signals for the display device 216. The circuitry of the playback decoder is chosen to take into account the order in which the record/playback device 184 has recorded the output of the storage device 194.

An embodiment of the arrhythmia detector 192 will now be described in greater detail with reference to Figure 2. The ECG signal appearing on line 188 is fed into a phase-locked loop 220 via an A/D converter 219. One such phase-locked loop is the RCA 4046, manufactured by the RCA Corporation, Solid State Division, Somerville, New Jersey, USA. The phase-locked loop contains an amplifier 222, the output of which is connected to one input of an exclusive-OR network 224 and to one input of a phase comparator 226. The output of a voltage-controlled oscillator (VCO) 228 is connected to the remaining input of the exclusive-OR network 224 and the remaining input of the phase comparator 226. The VCO requires an external capacitor C1, and two external resistors R1 and R2. Resistor R1 and capacitor C1 determine the frequency range of the VCO and resistor R2 enables the VCO to have a frequency offset. The output of the exclusive-OR network is fed to one input of a NOR-gate 230. Phase pulses from the phase comparator 226 are fed to the remaining input of the NOR-gate 230. The output of the NOR-gate 230 is fed into the input of an inverter 232 after passing through a resistor R3 in series with a diode D1. A capacitor C2 is connected between the input and the output of the inverter 232. One end of a resistor R4 is connected to the input of inverter 232 while the other end is connected to ground. The output of inverter 232 is fed to the input of an inverter 234 after passing through a resistor R5. The output of inverter 234 is fed to the input of an inverter 236 and to one input of a 3 input OR-gate 244. A resistor R7 is connected between the input of inverter 234 and the output of inverter 236. A voltage Vcc, which is 6 volts D.C., is delivered to the input of inverter 234 via a resistor R6.

A resistor R8 is connected between the output of the phase comparator 226 and the input of the VCO 228. The input of the VCO is also connected to ground via a capacitor C3 in series with a resistor R9. The capacitor C3 and the two resistors R8 and R9 form a two-pole low-pass filter to improve frequency capture range and lock-in speed. Two series resistors R10 and R11 are connected between the input of VCO 228 and the plus-input of an operational amplifier (op-amp) 238. The plus-input of op-amp 238 is also connected to ground via capacitor C5. One end of the capacitor C4 is connected to the series junction of resistors R10 and R11, while the other end is connected to the output of op-amp 238. A resistor R12 is connected between the output and the minus-input of op-amp 238. The output of the op-amp 238 is fed to the plus-input of an op-amp 240 via a resistor R15, and to the minus-input of an op-amp 242. A voltage VDD, which is 15 volts D.C., is delivered to the minus-input of op-amp 240. The minus-input of op-amp 240 is also connected to ground via a resistor R14. A resistor R16 is connected between the output and the minus-input of op-amp 240. The output of op-amp 240 is fed to the second input of OR-gate 244. A voltage VDD, which is 15 volts D.C., is delivered to the plus-input of op-amp 242 via a resistor R17. The plus-input of op-amp 242 is also connected to ground via a resistor R18. A resistor R20 is connected between the output and the plus-input of op-amp 242. The output of op-amp 242 is fed to the third input of OR-gate 244. Finally, the output of OR-gate 244 appears on lines 208 and 210 as the detection signal.

The phase-locked loop powered by a voltage Vcc consists of a low-power, linear VCO 228 and two different phase comparators 224 and 226 having a common signal-input amplifier 222 and a common comparator input denoted as 221. The output of the VCO is connected directly to the comparator input 221. Phase comparator 224 is an exclusive-OR network and has a typical

triangular phase-to-output response. With no signal or noise on the signal input, phase comparator 224 has an average output voltage equal to Vcc/2. Phase comparator 226 is an edge-controlled memory network which operates on the leading edges of the signal and comparator inputs. It continuously adjusts the VCO input voltage through the two-pole low-pass filter formed by capacitor C3 and resistors R8 and R9 for equal frequency and phase of the signal and comparator inputs. With no signal input, the phase-locked loop 220 using comparator 226 adjust the VCO 228 to its lowest possible frequency. The output of phase comparator 226 is a three-state output. Any time the phase comparator output is sinking or sourcing current into the low-pass filter the phase-pulses output is a logic 0. When the three-state output is in the high-impedance state, the phase-pulses output is a logic 1.

In operation, the ECG signal from the output of the A/D converter 219 is fed into the signal-in input of the phase-locked loop 220, which is responsive to the QRS pulses of the ECG signal. The phase-locked loop locks onto regular QRS pulses, but is unable to lock in irregular QRS pulses. The output of the NOR-gate 230 goes low when the loop 220 is locked and goes high when the loop is unlocked. Inverter 232, capacitor C2, diode D1 and resistors R3 and R4 form an integrator 231. The integrator 231 integrates the output of NOR-gate 230. Capacitor C1 provides a time delay, while resistors R3 and R4 adjust the rise and fall time, respectively, of the output of inverter 232. Inverters 234 and 236, and resistors R5 through R7 form a Schmitt trigger 233 having two switching thresholds; one near ground and the other near Vcc. The output of the Schmitt trigger appearing on line 235 is low when the loop 220 is locked and is high when the loop is unlocked.

The op-amp 238, capacitors C4 and C5, and resistors R10 through R12 form an active filter 229. Op-amp 240 and resistors R15 and R16 form a comparator 237. Op-amp 242 and resistors R19 and R20 form a comparator 239. The VCO input which is the voltage controlled oscillator's input is applied to the filter 229, which provides a D.C. voltage directly proportional to heart rate. The output of the filter 229 is fed to the pulse-input of comparator 237. The voltage divider formed by resistors R13 and R14 provides a reference voltage to the minus input of comparator 237. The output of comparator 237 is low when heart rate is normal and goes high when heart rate is higher than normal. The output of filter 229 is also fed to the minus-input of comparator 239. The voltage divider formed by resistors R17 and R18 provides a reference voltage to the plus-input of comparator 239. The output of comparator 239 is low when heart rate is normal and goes high when heart rate is lower than normal.

The output of OR-gate 244 is low when all of the outputs from the Schmitt trigger 233 and the comparators 237 and 239 are low, and goes high when any of said outputs goes high. The high output of OR-gate 244 provides the signal on line 208 to enable the record/playback device 184 and the signal on line 210 to cause the interval timer 212 to issue a time tag.

Obviously many modifications and variations of the present invention are possible in light of the above teachings. It is therefore to be understood that within the scope of the appended claims, the invention may be practiced otherwise than as specifically described.

CLAIMS

1. Apparatus dedicated to a single patient for monitoring the operation of an automatic defibrillator implanted in the patient, the apparatus comprising:

first detector means responsive to deliverance of defibrillating energy by said implanted defibrillator for triggering the storage of data related to said deliverance of defibrillating energy;

storage means for durably storing said data;

external receiving means for receiving said data; and

telemetry means for transmitting said data from the patient to said external receiving means.

2. The device recited in claim 1 wherein said data are at least one of disturbances in cardiac electrical activity, defibrillation pulses, ECG signals and time tags.

3. The device recited in claim 1 wherein said telemetry means is external to said recipient, and includes external electrodes on said recipient for sensing the electrical activity of the heart.

4. The device recited in claim 1 wherein said telemetry means is implanted with said defibrillator.

5. The device recited in claim 1 and further comprising means for permanently recording said data transmitted to said external receiving means.

6. The device according to claim 1 wherein said storage means comprises:

first storage means having a predetermined small capacity for temporarily storing and updating a small portion of said data; and

second storage means for durably storing the portion of the data occurring after the deliverance of defibrillating energy.

7. The device according to claim 6 wherein said receiving device includes a tape recorder having a tape for durably storing the data stored in said first storage means and said data stored in said second storage means.

8. The device of claim 1 further comprising means for monitoring data relating to cardiac electrical activity, and wherein said first detector means, in response to said deliverance of defibrillating energy, triggers the storage of data related to said cardiac electrical activity, said external receiving means receives said data related to said cardiac electrical activity, and said telemetry means transmits said data related to said cardiac electrical activity from said patient to said external receiving means.

9. The device of claim 8 further comprising

means for formatting said received data related to said cardiac electrical activity and said deliverance of defibrillating energy to provide information indicative of whether or not said deliverance of defibrillating energy was made in response to the detection of fibrillation by said implanted defibrillator.

10. The device of claim 9 further comprising second detector means responsive to events characteristic of a possible fibrillation episode for triggering the storage of said data related to said cardiac electrical activity.

11. Apparatus dedicated to a single patient for monitoring the operation of an automatic defibrillator implanted in the patient, the apparatus comprising:

a first unit adapted to be worn by the patient, said first unit comprising,

sensing means for sensing electrical activity associated with the patient's heart as a first signal, and

transmitting means for transmitting said sensed first signal; and

a second unit capable of easily being carried and moved, said second unit comprising,

receiving means for receiving said transmitted first signal,

detector means in circuit with said receiving means and responsive to a defibrillation attempt for triggering the storage of data related to said attempt, and

storage means for durably storing said data related to said attempt.

12. The device of claim 11 wherein said detector means is an arrhythmia detector.

13. The device according to claim 11 wherein said second unit further comprises means for retrieving from said storage means said durably stored data related to said attempt, and

means for displaying said retrieved output in eye-readable format.

14. The device according to claim 11 wherein said first unit further comprises internal timing means for providing a time tag, and means responsive to said detector means for causing said time tag to be durably stored in said storage means.

15. The device according to claim 11 wherein said storage means includes a cassette tape recorder having a magnetic tape.

16. The apparatus of claim 11 wherein said second unit further comprises,

means responsive to said received first signal for producing a second signal when said received first signal falls below a predetermined magnitude, and

means for producing an audible tone in response to said second signal to alert the patient that said first signal is not being received by said second unit.

17. The apparatus of claim 11 wherein said second unit further comprises means responsive to said received first signal for producing a second signal when said received first signal falls below a predetermined magnitude, and for disabling said storage means in response to said second signal.

18. Apparatus dedicated to a single patient for monitoring the operation of an automatic defibrillator implanted in the patient, the apparatus comprising:

first detector means responsive to events characteristic of a possible fibrillation episode for triggering the storage of data related to said possible fibrillation episode;

second detector means responsive to deliverance of defibrillating energy by said implanted defibrillator for triggering the storage of data related to said deliverance of defibrillating energy;

storage means for durably storing the data related to said possible fibrillation episode and said deliverance of defibrillating energy;

external receiving means for receiving the data related to said possible fibrillation episode and said deliverance of defibrillating energy; and

telemetry means for transmitting the data related to said possible fibrillation episode and said deliverance of defibrillating energy from the patient to said external receiving means.

19. An implantable automatic defibrillator including treatment verification capabilities, said defibrillator comprising:

sensing means for sensing electrical activity associated with the heart of a wearer;

detector means receiving said electrical activity from said sensing means for detecting cardiac arrhythmias including fibrillation;

signal-generating means for issuing signals in response to the detection of arrhythmias by said detector means;

storage and discharge means for first storing and then automatically discharging defibrillating energy through the heart of the wearer;

charging means for charging said storage and discharge means with said defibrillating energy;

means creating an electrical link between said signal-generating means and said charging means for activating said charging means upon detection of fibrillation by said detector means;

storage means for durably storing the electrical activity sensed by said sensing means; and

means creating an electrical link between said signal-generating means and said storage means for activating said storage means upon detection of an arrhythmia by said detector means.

20. The defibrillator of claim 19 wherein said storage and discharge means and said charging means are activated simultaneously in response to a single signal produced by said signal-generating means.

21. Apparatus for monitoring the operation of an automatic defibrillator implanted in a patient, the apparatus being substantially as herein described with reference to the accompanying drawings.

New claims or amendments to claims filed on 16 Nov. 1981.

Claims 19 and 20 deleted, claim 21 re-numbered 19.

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